

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IN2004/000341

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D495/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, CHEM ABS Data, BEILSTEIN Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/051362 A (TEVA PHARMACEUTICAL INDUSTRIES LTD; TEVA PHARMACEUTICALS USA, INC; LIF) 26 June 2003 (2003-06-26) cited in the application page 6, lines 18-23; examples 21,27,42-44 page 24, paragraph 1	1-15,20
X		16-19, 21,23,24
P,A	WO 2004/081016 A (CADILA HEALTHCARE LIMITED; LOHRAY, BRAJ, BHUSHAN; LOHRAY, VIDYA, BHUSH) 23 September 2004 (2004-09-23) examples 15,21	11,13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

20 July 2005

Date of mailing of the international search report

05.08.05

Name and mailing address of the ISA

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Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 22
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 22

Claim 22 is insufficiently disclosed. The technical features of this claim are i) the stirring of amorphous clopidogrel bisulfate in MTBE and ii) the removal of the solvent to give form II. W003/051362 discloses an example (ex. 21) in which (S)-(+)-Clopidogrel bisulfate in a non-crystalline form (white foam) is stirred in MTBE and a solid is recovered. This solid is a mixture of amorphous form and form I. Thus, it would appear that essential technical features are missing from this claim, as the claimed process does not reliably and inevitably give the desired form II. As there are no preferred embodiments for this claim (i.e. dependent claims) it is not clear which further feature(s) could be inserted in this claim in order to give a process which reproducibly gives the desired polymorph. It was therefore not possible to perform any meaningful search or examination of the novelty and inventive step of this claim.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-9

processes for the preparation of hydrated form of amorphous
(S)-(+)-Clopidogrel bisulfate.

2. claims: 10-21

processes for the preparation of form I of
(S)-(+)-Clopidogrel bisulfate.

3. claim: 22

process for the preparation of form II of
(S)-(+)-Clopidogrel bisulfate.

4. claims: 23,24

Methods of treating cardiovascular and related diseases
using (S)-(+)-Clopidogrel bisulfate; uses of
(S)-(+)-Clopidogrel bisulfate for the preparation of a
medicament for treating cardiovascular and related diseases.

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Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03051362	A	26-06-2003	US 2003114479 A1	19-06-2003
			AU 2002366383 A1	30-06-2003
			CA 2470479 A1	26-06-2003
			EP 1467735 A2	20-10-2004
			HU 0402485 A2	28-04-2005
			JP 2005514387 T	19-05-2005
			WO 03051362 A2	26-06-2003
			US 2003225129 A1	04-12-2003
WO 2004081016	A	23-09-2004	WO 2004081016 A1	23-09-2004
			AU 2003238664 A1	30-09-2004